Exhibit 140

FDA STATEMENT

FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues

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Statement From:

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Last summer, the FDA learned and reported that some generic versions of the angiotensin II receptor blocker (ARB) medicines contain nitrosamine impurities that don't meet the agency's safety standards. ARBs, including valsartan, irbesartan, losartan and others, are a class of medicines used to treat high blood pressure and heart failure. Nitrosamine impurities, including N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), are probable human carcinogens. These two substances are known environmental contaminants and found in water and foods, including meats, dairy products and vegetables. But their presence in drug products is not acceptable.

We were deeply concerned when we learned about the presence of these impurities. We immediately undertook a major operation to investigate and to identify the root causes for the presence of these impurities in some ARB drugs, and to work with companies to address the risks that the impurities pose to patients.

Our analysis of NDMA found that the risk to patients based on the maximum possible exposure appears to be small. That doesn't diminish our concern and our determination to find out how these impurities occurred in the first instance. We're committed to implementing measures to prevent these impurities from occurring in the manufacturing process in the future. Our ultimate goal is to ensure that these impurities are not present in finished drug products, or their components (including active pharmaceutical ingredients, or API).

There remains a great deal of public interest in this matter. Today, we want to provide an update on this ongoing investigation and outline the steps we've taken to identify the root causes of the nitrosamine impurities and to prevent a recurrence of this episode in the future. This continues to be an exhaustive effort led by a multidisciplinary team of chemists, toxicologists, physicians, pharmacists, communication specialists, investigators and analytical laboratory staff from across the FDA and in collaboration with global regulators.

While we're still investigating the root causes of the impurities, our ongoing effort has determined that the impurities may be generated when specific chemicals and reaction conditions are present in the manufacturing process of the drug's API, and may also result from the reuse of materials, such as solvents.

This issue surfaced in the summer of 2018, when the FDA was informed that API manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. (ZHP), in Linhai, Taizhou Zhejiang China for some generic valsartan-containing medicines contained NDMA, posing a potential safety concern.

Since then, the FDA and additional manufacturers of other ARB medicines have identified more cases of NDMA impurities, as well as NDEA impurities. We've placed a ZHP facility on import alert to stop all its API and finished drugs made using ZHP's API from legally entering the U.S. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control and cross contamination from one manufacturing process line to another. It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice (CGMP) inspection. Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise.

We've also worked with manufacturers of all ARB medicines to recall any product that poses a risk to patients. Because of the way API is distributed in the supply chain, one source of contaminated API can impact multiple products. As part of this continuing process, last week, we alerted patients and health care professionals to a voluntary recall of one lot of irbesartan and seven lots of irbesartan and hydrochlorothiazide (HCTZ) combination tablets distributed by Solco Healthcare LLC, a Prinston Pharmaceutical Inc. subsidiary. The recall is due to unacceptable amounts of NDEA in the irbesartan API manufactured by ZHP. We will continue to keep the public updated via our website (/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications) of all products being recalled. While we acted aggressively to address the issue once we became aware of it, we must also answer the critical question of, why weren't these impurities detected earlier? We've also been asked whether the FDA could have prevented this from occurring if we had done something differently during surveillance inspections in the preceding years.

We want to lay out the many steps we take to mitigate these kinds of risks.

We engage experts in organic chemistry to detect circumstances that can create the risk for these kinds of impurities to be introduced as a by-product of the manufacturing process or changes made in that process. We also work with international regulators to create standards for mitigating the risk of this type of chemical impurity, known as a "genotoxic" impurity. These chemicals, including NDMA and NDEA, are of special concern to global regulators because, unlike most impurities in drugs, they have the potential to cause harm at very low levels. That's why we have robust policies and procedures in place to guard against these risks.

In March 2018, the FDA issued a guidance (/media/93672/download) for manufacturers that lays out risk assessments that manufacturers can use to evaluate the presence of genotoxic impurities. This is an internationally-harmonized guidance that regulators and industry have agreed to. The FDA reviews information on impurity testing in product applications and when inspecting facilities. Manufacturers must test for known impurities during their manufacturing processes.

We review information about potential impurities that can occur during manufacturing in applications, including requests that sponsors submit to change some aspects of the manufacturing process, which could create new risks. Specifically, our chemists review applications and referenced information to look for steps and changes where risks could be introduced. To implement a risk assessment for any genotoxic impurity, there must be recognition that it can occur in a product's manufacturing. The guidance lays out the conditions under which these risks can occur and steps that manufacturers should take to test for these potential impurities. Now that we've uncovered the risk of nitrosamine impurities in the manufacturing steps involved in ARBs, we'll incorporate the findings into ongoing policy development.

In addition to our policy work, the FDA inspects manufacturing facilities worldwide. Generally during CGMP inspections, we review the records that manufacturers must maintain regarding required impurity testing. However, the impact of this record review depends on manufacturers conducting appropriate tests that are capable of detecting the impurity. Tests are selected based on assessments of what impurities may develop as a result of the manufacturing process. In other words, it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for.

Our investigation into ZHP's process identified that a change made to the manufacturing process likely led to this impurity, and that the impurity went undetected by global regulators, including the FDA, for a period of time. Before we undertook this analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing process.

This is troubling to us and we know it's troubling to the public. This concern is appropriate. Among other steps, we need to take actions that would prevent a similar situation from occurring. We are making important strides at understanding how these impurities occurred, mitigating the risk to patients and learning what steps need to be taken to prevent this from occurring again in the future.

One challenge we've faced is that NDMA's properties make it hard to detect in standard laboratory testing – the kind of testing results that are reviewed during a surveillance inspection. In St. Louis, the FDA maintains one of the most advanced pharmaceutical laboratories of any regulatory agency in the world. As soon as we became aware of the presence of nitrosamine impurities in certain ARB medicines, we began collecting samples of all ARB API and medicines marketed in the U.S. to test these products specifically for NDMA. More testing found NDEA, also a probable human carcinogen, in other valsartan products and other ARBs from different manufacturers.

During this time, our scientists have developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines. We've shared these tests on our website to help manufacturers and other regulators evaluate these products as well. To determine if ARB medicines contain these impurities, FDA scientists developed three testing methods. These include the (GC/MS) headspace method (/media/115965/download), the combined headspace method (/media/115965/download), and the combined direct injection method (Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA)). These testing methods can be used for evaluating both drug substances (API) and finished drug products.

Medicines that contain NDMA or NDEA above certain limits (/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan) (see 12/19/2018 update) pose an unacceptable risk to patients, and ARBs that contain impurities above these levels are being recalled. We've also posted lists of valsartan (/media/118231/download), losartan (/media/119422/download), and irbesartan (/media/118233/download) products affected by the recalls. We'll continue to update these lists as new information develops. And we'll continue to work with manufacturers to ensure all affected products are quickly removed from market. We're also working with API makers to ensure that they fix their processes and cease distribution of affected API.

We know patients rely on these medicines. Part of our work throughout this process has been to mitigate and prevent shortages, where possible. Currently, valsartan products are in shortage, and we know that other types of products may fall into shortage soon. That's why the agency has also evaluated safety data for NDMA and NDEA to determine interim acceptable intake levels for

these impurities in the ARB class of medicines. While consumers should limit exposure to NDMA and NDEA, these impurities exist in other ingested products, such as some charcoal grilled food items. And so, our goal is to balance the risk of patients ingesting low levels of the impurities (below the interim acceptable levels) for a short period of time with the risk that there is a shortage of certain ARBs, which may impact patients' ability to access the medicine they need. We remind patients taking these medications or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

Overall, the risk to individual patients remains very small, although this doesn't diminish the significance of this episode or our concerns. FDA scientists estimate that if 8,000 people took the highest daily valsartan dose (320 mg) that contained NDMA, for four years (the time we think the affected products had been on the U.S. market), there may be one additional case of cancer beyond the average cancer rate among those 8,000 Americans. The vast majority of patients exposed to NDMA through ARBs received much smaller amounts of the impurity than this worst-case scenario. Since not all ARBs are affected, it's very likely that a patient taking an ARB for four years would not have always received one of the affected products. We're still seeking to similarly quantify the risk from NDEA and plan to communicate our findings as soon as possible.

Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise. As part of this process, the FDA has identified specific factors in manufacturing processes that may contribute to the formation and presence of NDMA and NDEA. Through our investigation, we're working to ensure that other manufacturing conditions don't contribute to NDMA, NDEA, or related impurities in finished drug products. We'll use the information we've learned about these impurities when reviewing applications, assessing manufacturing changes and conducting inspections. Now that they are aware that certain conditions result in the formation of nitrosamines, manufacturers using processes at risk for these impurities are expected to test for them to ensure that active ingredients and finished products are free of detectable levels of a nitrosamine impurities resulting in drug products that that are safe for patients.

While the total exposure to these impurities for most patients was small, we are deeply concerned that patients were exposed to this impurity in the first place and that the presence of nitrosamines went undetected for a period of time. The potential for the development of genotoxic impurities during manufacturing processes is an area of intense focus. We'll continue to improve our science and standards for detecting and preventing these risks.

We'll also continue to keep the public informed on our website (FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan), which contains most current information. Patients and providers can also send email to druginfo@fda.hhs.gov (/about-fda/page-not-found) or call 855-543-3784. We're also encouraging submission of any information related to potential side effects to our MedWatch program (http://wcms.fda.gov/ucm/resources/wcm/3rdparty/fckeditor/editor/[!--$wcmUrl('nodelink','2237')--]).

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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